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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/852,495	05/07/1997	DAVID A. RUDDY	17957-000110	7064

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EXAMINER

DECLOUX, AMY M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/852,495

Applicant(s)

Ruddy et al

Examiner

DeCloux, Amy

Art Unit

1644



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 14, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

4) Claim(s) 29-99 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 29-99 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

DETAILED ACTION

1. Note The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.
2. Applicant's amendment, filed 1/14/02 (Paper No. 31), originally mailed 10/24/01, is acknowledged.
3. The rejections of record can be found in the previous Office Action, mailed 4-25-01 (Paper No. 27).

In view of applicant's amendment and remarks filed 1/14/02 (Paper No. 31), the 112 first paragraph and utility 101 rejections have been maintained.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. MAINTAINED Claims 29-48 and 69-79 and newly added claims 80-99 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant traverses the rejection on the grounds that applicants provide structural information for every claimed polynucleotide, and that consequently one of skill in the art can recognize all the members of each of Applicant's claimed genera.

However, the examiner notes that applicant is claiming a nucleotide that comprises over 235 kilobases of DNA. The instant specification discloses approximately 400 nucleotide polymorphisms, most of which are 1-4 base pair changes, the remaining few consist of up to only about 15 base pair alterations. However, the instant specification fails to provide sufficient written description regarding the more than 200 kilobases of DNA recited in the instant claims, because there is no function associated with more than 200 kilobases of DNA, and one of skill can not even distinguish coding regions from noncoding regions. Therefore, one of skill could not visualize the recited nucleotides based on the description of a few bases which applicants disclose as being one of approximately 400 polymorphic sites

correlated with the likelihood of having the disease associated allele 24d1 of the Hereditary Hemochromatosis gene or the complement thereof.

Applicant traverses the phrase "comprising" as transition language because the PTO routinely deals with fragment of SEQ ID NO:s. However the examiner notes generally a recited fragment is part of a single gene. And with regard to the patents cited by applicant, each patent application is prosecuted on the basis of its own merits, not on the basis of other issued patents. As discussed above the open "comprising" language encompasses nucleotide sequences which are not described.

Applicant states that an HH-associated gene, as such, is not being claimed, but what is being claimed is polynucleotide useful for determining whether a subject has an increased chance of having the disease causing 24D1 allele of the HH gene. However, the examiner notes that intended use is not descriptive of the entire 23KB piece of DNA claimed by reciting the open language.

Applicant also gives several lines of arguments supporting that idea the recited polymorphic sites are of predictive value. The arguments are based on the idea that polymorphic markers can be located some distance from the gene under consideration, with which the examiner agrees. Further, it is acknowledged by the examiner that the instant specification discloses the precise sequence and location of the HH gene. However, these arguments do not overcome the written description rejection over the content of the recited claims, essentially for the reasons discussed above.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive, and the rejection is maintained, essentially for the reasons of record.

6. **35 U.S.C. § 101 reads as follows:**

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

7. Claims 29-79 and newly added claims 80-99 are rejected under 35 USC 101 because the claimed invention lacks a credible asserted utility or a well established utility.

Applicant traverses the rejection on the grounds that the claimed polynucleotides can be used to determine whether a subject has an increased chance of being heterozygous or homozygous for the disease-causing 24D1 allele of the HH gene. The instant specification discloses on page 11 that the 397 polymorphisms listed in Table I were identified by comparison of the sequence of 35 kilobases of DNA from an affected

individual homozygous for the common ancestral Human hemochromatosis mutation with that of DNA from an unaffected individual. However, the instant examiner maintains the position of the previous examiner, that the instant specification does not disclose how or if said polymorphisms are actually linked with the common ancestral Human hemochromatosis mutation, with two exceptions (that of mutations at base 35,983 and at 61,465, wherein polymorphism at said site were found at almost 80% of HH affected individuals as opposed to just around 5% of unaffected individuals, as disclosed on page 27 of the instant specification). Applicants purport, but do not show, that the remaining polymorphisms are linked based on gene mutation frequencies and map distance.

However, even considering that the recited polymorphisms are linked to the common ancestral Human hemochromatosis mutation, the disclosed asserted linkage utility is specific and substantial only for short oligonucleotides that contain a polymorphism, but not for the entire 35 KB DNA region that comprises each of said polymorphisms. Applicant does not disclose the utility of the recited DNA sequence, or even identify coding versus noncoding regions of the recited 35KB of DNA. Therefore, the claimed nucleotides lack a credible asserted utility or a well established utility.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive, and the rejection is maintained essentially for the reasons of record.

8. Claims 29-79 and newly added claims 80-99 are also rejected under 35 USC 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant contends that the instant rejection should be withdrawn based on the arguments set forth in the traversal of the 101 utility rejection. However, since said 101 utility rejection is being maintained for the reasons discussed above, the instant 112 first how-to-use rejection associated with the maintained 101 utility rejection has been maintained, essentially for the reasons of record.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The 12CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640, Technology Center 1600
March 14, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644